

§ 730.1

the firm or the product. Any representation in labeling or advertising that creates an impression of official approval because of such filing or such number will be considered misleading.

[57 FR 3130, Jan. 28, 1992]

PART 730—VOLUNTARY FILING OF COSMETIC PRODUCT EXPERIENCES

Sec.

730.1 Who should file.

730.2 Time for filing.

730.3 How and where to file.

730.4 Information requested.

730.5 Additions or amendments to reports.

730.6 Notification to person submitting reports.

730.7 Confidentiality of reports.

730.8 Misbranding by reference to filing; filing does not constitute an admission.

AUTHORITY: Secs. 201, 301, 601, 602, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 361, 362, 371, 374).

SOURCE: 39 FR 10062, Mar. 15, 1974, unless otherwise noted.

§ 730.1 Who should file.

Every person who is a manufacturer, packer, or distributor of a cosmetic product is requested to file a Form FD-2704 (Cosmetic Product Experience Report), with respect to all reportable experiences which have been reported to him concerning any of his cosmetic products in commercial distribution, regardless of whether he is a participant in the voluntary program to register cosmetic product establishments pursuant to part 710 of this chapter, and regardless of whether he is a participant in the voluntary program to file cosmetic product ingredient and raw material composition statements pursuant to part 720 of this chapter. In addition, every person who is a manufacturer, packer, or distributor of a cosmetic product, whether or not he has received any information concerning a reportable experience in regard to any of his cosmetic products in his system of commercial distribution, is requested to file a Form FD-2706 (Summary Report of Cosmetic Product Experience by Product Categories). This request extends to any foreign manufacturer, packer, or distributor of a

21 CFR Ch. I (4–1–96 Edition)

cosmetic product imported into any State. No filing fee is required.

[39 FR 10062, Mar. 15, 1974, as amended at 46 FR 38073, July 24, 1981]

§ 730.2 Time for filing.

(a) Reportable experiences should be reported on an annual basis, for the period January through December, not later than 60 days after the close of the reporting period.

(b) A summary report of cosmetic product experience by product categories should be filed on an annual basis, for the period January through December, not later than 60 days after the close of the reporting period.

[51 FR 25687, July 16, 1986]

§ 730.3 How and where to file.

Form FDA 2704 (Cosmetic Product Experience Report) and Form FDA 2706 (Summary Report of Cosmetic Product Experience by Product Categories) are obtainable from, and the completed forms should be mailed or delivered to, Cosmetic Product Experience Report, Center for Food Safety and Applied Nutrition (HFS-100), Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

[51 FR 25687, July 16, 1986, as amended at 61 FR 14481, Apr. 2, 1996]

§ 730.4 Information requested.

(a) Form FD-2704 (Cosmetic Product Experience Report) requests the following information:

(1) The name of the person (manufacturer, packer, or distributor) designated on the label of the cosmetic product.

(2) Time period covered by the report.

(3) The complete name of the cosmetic product exactly as it appears on the label of the product.

(4) The cosmetic product category, as set forth in § 720.4(c) of this chapter and on the form, which best describes the product's intended use.

(5) Total number of reportable experiences during this reporting period and number of these experiences requiring professional medical attention.

(6) Total number of product units of the cosmetic product estimated to have been distributed to consumers during this reporting period.